

**REMARKS**

The Official Action dated April 9, 2010 has been carefully considered. Accordingly, the present Amendment is believed sufficient to place the present application in condition for allowance. Reconsideration is respectfully requested.

By the present amendment, claims 1 and 23 are amended to recite the employment of the system of claim 12, and for matters of form. Claims 4 and 13 are also amended for matters of form. Claim 12 is amended to recite a “white” light source as described in the specification, for example, at page 8, first paragraph, and to recite that the data matrixes represent red, blue and green colors, respectively, as set forth in the specification, for example, at page 4, fourth paragraph. Claims 14, 15 and 19 are amended to recite “polarized light from the light source and filter” in place of “said illuminating light.” Claims 36-38 are added, support for which may be found in the specification, for example in the sentence bridging pages 9-10. It is believed that these changes do not involve any introduction of new matter, whereby entry of the amendments is in order and is respectfully requested.

In the Official Action, the restriction requirement was made final. Claims 1-11 and 23-35 were presumably withdrawn, although this is not specifically indicated in the Official Action. As claims 1 and 23 have been amended to depend from claim 12, rejoinder of claims 1 and 23, together with claims 2-4 and 24-29 respectively dependent thereon, upon allowance of claim 12 is respectfully requested.

Claims 13-15 were rejected under 35 U.S.C. §112, second paragraph, on the basis that “the vasodilatation” in claim 13 and “said illuminating light” in claims 14 and 15 had no antecedent basis. This rejection is traversed. Claim 13 as amended does not require antecedent

basis for the term “vasodilatation” and claims 14 and 15 are amended to recite “polarized light from the light source and filter” in accordance with claim 12, in place of “illuminating light.” Accordingly, claims 13-15 comply with 35 U.S.C. §112, second paragraph, and the rejection has been overcome. Reconsideration is respectfully requested

Claims 12-15 and 20-22 were rejected under 35 U.S.C. §103(a) as being unpatentable over the Zinser et al U.S. Patent No. 5,620,000 in view of the Gardin et al U.S. Patent No. 4,913,159 and either the Wunderman et al U.S. Patent No. 6,122,042 or the Crutchfield et al U.S. Publication No. 2002/0091320. Claims 16-18 were rejected under 35 U.S.C. §103(a) as being unpatentable over these references and further in view of the Nakakuki U.S. Publication No. 2004/0208393, while claim 19 was rejected under 35 U.S.C. §103(a) as being unpatentable over these references in view of the Takahashi et al U.S. Patent No. 4,366,529.

The Examiner asserted that Zinser et al teach a method for measuring the flow rate of blood using a laser diode and a polarizer and by detecting backscattered or reflected light from an object, referring particularly to column 7, lines 48-67. Zinser et al was also asserted to disclose a computer and electric monitoring control system for analyzing detected light intensities to obtain flow rates by collecting a matrix of MxN measured values and a second matrix of measured values which are subject to Fourier transform and displaying the matrices on a computer screen. The Examiner relied on Gardin et al as teaching a Doppler blood flow imaging wherein the velocity of blood flow in a vessel is represented by color images on a display and on Wunderman et al and Crutchfield et al as teaching analog to digital converters. The Examiner concluded it would have been obvious to combine Zinser et al with Gardin et al by using red or blue to represent blood flow or velocity to increase visualization and with

Wunderman et al or Crutchfield et al by using a photodetector array and analog-to-digital converting for computer compatibility and convenience. Finally, the Examiner relied on Nakakuki as teaching that image data corresponding to red, green and blue may be divided into a group of pixels in a matrix and the luminance for each pixel may be represented as 8-bit data and converted into a numerical value on a scale, and on Takahashi et al as teaching the use of optical fibers to direct an illuminating light beam to a portion of a body cavity.

These rejections are traversed and reconsideration is respectfully requested. More particularly, according to claim 12, the system for determining microcirculation of a living tissue according to the present invention comprises (i) a white light source and a filter capable of illuminating a tissue surface with polarized light, (ii) a polarizing filter for collecting backscattered light; (iii) a photosensitive array capable of detecting the backscattered and polarized light and converting the detected light to a collected information of digital values; and (iv) a computing device receiving said collected information and adapted to separate it into data matrixes representing red, blue and green colors, respectively, and employing an algorithm using the data matrixes to generate an output data matrix representing the microcirculation. Thus, the presently claimed system determines microcirculation based on the concentration of red blood cells. As explained in the specification, for example at pages 8-9, “red” photons have a tendency to be less absorbed by the red blood cells than “green” and “blue” photons, and, consequently, the more red blood cells in the tissue, indicative of a higher degree of vasodilatation, the higher is the absorption of “green” and “blue” photons in relation to the absorption of “red” photons in the polarized white light which reaches the tissue surface. The photosensitive array detects the backscattered and polarized light, indicative of the degrees of absorption of the respective

photons, and converts the detected light to a collected information of digital values, which the computing device then separates into data matrixes representing red, blue and green colors, respectively, and employs an algorithm using the data matrixes to generate an output data matrix representing the microcirculation.

The system of the present invention is significantly distinguishable from the cited combinations of references. That is, Zinser et al disclose a laser Doppler system which measures a blood flow rate rather than a concentration of red blood cells as is the case with the present system. Zinser et al employ a laser, i.e., monochromatic light, rather than a white light source which is provided in the present system. Further, the Zinser et al laser Doppler system provides single point measurement wherein N measurements are taken at a single point. Applicants find no teaching or suggestion by Zinser et al of a computing device which receives collected information in a digital form and which is adapted to separate it into data matrixes representing red, blue and green colors, respectively, which can then be used to generate an output data matrix representing the microcirculation, as required by claim 12. The presently claimed system is therefore significantly distinguishable from Zinser et al.

The deficiencies of Zinser et al are not resolved by the secondary references. Gardin et al disclose a Doppler imaging system using ultrasonic pulses for measuring blood flow through a narrow orifice (see column 4, lines 3-12). One of ordinary skill in the art will appreciate that such an ultrasound system is not relevant to an optical system as presently claimed. Additionally, while the Gardin et al system represents the measured flow in color images on a display, with different colors representing different velocities and different directions, the Gardin et al system does not employ a white light source and does not include a photosensitive array

which detects backscattered and polarized light, indicative of the degrees of absorption of the respective photons, and converts the detected light to a collected information of digital values, or a computing device which then separates the collected information into data matrixes representing red, blue and green colors, respectively, as required by claim 12. Further, Applicants find no apparent reason of record for one of ordinary skill in the art to use any of the Gardin et al teachings to modify the Zinser et al system.

Crutchfield et al, like Gardin et al, disclose a Doppler imaging system using ultrasonic pulses (see paragraph [0064]). As noted, one of ordinary skill in the art will appreciate that such an ultrasound system is not relevant to an optical system as presently claimed. Although Crutchfield et al disclose an analog-to-digital converter, the Crutchfield et al system does not employ a white light source and does not include a photosensitive array which detects backscattered and polarized light, indicative of the degrees of absorption of the respective photons, and converts the detected light to a collected information of digital values, together with a computing device which then separates the collected information into data matrixes representing red, blue and green colors, respectively, as required by claim 12. Further, Applicants find no apparent reason of record for one of ordinary skill in the art to use any of the Crutchfield et al teachings to modify the Zinser et al system.

Wunderman et al disclose an apparatus for photometric analysis and/or identification of properties of a material object. The apparatus comprises a collection of light sources having substantially distinct wavelength envelopes and a collection of spatially distributed light detectors. While Wunderman et al may teach a photodetector array, Applicants find no teaching of a system comprising the combination of a white light source, a photoarray and a computing

device which separates collected information into data matrixes representing red, blue and green colors, respectively, as required by claim 12. Further, Applicants find no apparent reason of record for one of ordinary skill in the art to use any of the Wunderman et al teachings to modify the Zinser et al system.

Nakakuki is directed to an image processing device which is adapted to determine if a spectrum of a predetermined physical quantity in image data has a plurality of peaks. An image capturing unit such as a camera is employed. However, Nakakuki is not directed to systems or methods for determining microcirculation and provides no teaching or suggestion of a system for determining microcirculation based on a measured concentration of red blood cells. Importantly, Applicants find no apparent reason of record for one of ordinary skill in the art to use any of the Nakakuki teachings to modify the monochromatic laser system of Zinser et al, particularly along the lines of the present system.

Finally, Takahashi et al disclose an illumination device for observing and photographing a portion of a body cavity to be examined with an endoscope and including a bundle of optical fibers. However, the Takahashi et al teachings are not directed to systems or methods for determining microcirculation and they provide no teaching or suggestion of a system for determining microcirculation based on a measured concentration of red blood cells. Importantly, Applicants find no apparent reason of record for one of ordinary skill in the art to use any of the Takahashi et al teachings to modify the system of Zinser et al, particularly along the lines of the present system.

In determining patentability under 35 U.S.C. §103, it is necessary to determine whether there was an apparent reason to combine known elements in the fashion of the claims at issue,

*KSR International Co. v. Teleflex, Inc.*, 550 US 398, 418 (2007). Applicants find no evidence of record which would indicate any apparent reason to one of ordinary skill in the art to modify and supplement the teachings of Zinser et al to result in a system as presently claimed. The deficiencies of the combinations of cited references are particularly evident in view of the failure of any of the cited references to teach, suggest, or recognize that microcirculation may be determined based on red blood cell concentration. Thus, the requisite showing that those of ordinary skill in the art would have had some apparent reason to modify the Zinser et al system in a way that would result in the claimed system has not been made.

Accordingly, the system for determining microcirculation according to claim 12, and claims 13-22 dependent thereon, is nonobvious over and patentably distinguishable from the cited combinations of references based on Zinser et al, and the rejections under 35 U.S.C. §103 have been overcome. Reconsideration is respectfully requested.

It is believed that the above represents a complete response to the Official Action and places the present application in condition for allowance. Reconsideration and an early allowance are requested. In the event that the application is not in condition for allowance, the Examiner is encouraged to call the undersigned to resolve any outstanding matters. Please charge any fee required with this response to Deposit Account No. 503915.

Respectfully submitted,

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